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Virginia Board of Pharmacy News

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Legislative Update

Virginia's 2015 General Assembly Legislative Session ended on February 27, 2015. Several bills will become law on July 1, 2015, that may affect your practice.

- **House Bill (HB) 1736** requires a wholesale distributor or nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances (CS) to notify the Virginia Board of Pharmacy within five days of the cessation.
- **HB 1737** creates a new regulatory framework for permitting outsourcing facilities that compound sterile drugs and are located within the Commonwealth, along with registering nonresident outsourcing facilities shipping their product into the Commonwealth. The bill also amends §54.1-3410.2 of the Drug Control Act by limiting the circumstances under which a pharmacy may provide compounded drugs to practitioners of medicine, osteopathy, podiatry, or dentistry for office use. Effective July 1, 2015, a pharmacy may only provide a reasonable amount of compounded drugs to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded drug products to practitioners of veterinary medicine for office-based administration to their patients. The bill further requires the Board to promulgate emergency regulations to implement the provisions of the act to be effective within 280 days of its enactment. The Board Regulation Committee will consider draft language for the regulations at its May 11, 2015 committee meeting and present to the full Board for consideration on June 15, 2015.
- **HB 1914** provides that a prescriber may authorize pharmacists, pursuant to an oral or written order or standing protocol, to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.
- **HB 2192** requires facilities from which practitioners of the healing arts (practitioners of medicine, osteopathy, and podiatry) dispense CS to obtain a permit from the Board of Pharmacy. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell CS shall be exempt from fees associated with obtaining and renewing such permit. The bill further requires the Board to promulgate emergency regulations to implement the provisions of the act to be effective within 280 days of its enactment. The Board Regulation Committee will consider draft language for the regulations at its May 11, 2015 committee meeting and present to the full Board for consideration on June 15, 2015. Note: The requirement for the facility to obtain a permit is in addition to the requirement for the individual to obtain a license to dispense, a model analogous to the permitting of a pharmacy and the licensing of an individual pharmacist.
- **HB 1839** conforms the Drug Control Act with recent federal scheduling actions by removing hydrocodone combination products from Schedule III, which thereby places these drug products into Schedule II, and places alfaxalone, suvorexant, and tramadol into Schedule IV. Note: Effective July 1, 2015, and pursuant to Regulation 18VAC 110-20-240, the requirement to perform a monthly perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly, shall include all hydrocodone combination products.
- **HB 1735** enables an optometrist to prescribe and administer, within his or her scope of practice, Schedule II CS consisting of hydrocodone in combination with acetaminophen, and Schedule III through VI CS and devices as set forth in the Drug Control Act to treat diseases and abnormal conditions of the human eye and its adnexa.

continued on page 4

FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

continued from page 1

- **HB 2063** addresses the establishment of a bona fide practitioner-patient relationship for the purpose of prescribing Schedule VI drugs to a patient via telemedicine services.
- **HB 1458,** among the allowances, expands the former naloxone pilot by authorizing pharmacists to dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber and in accordance with protocols developed by the Board of Pharmacy in consultation with the Virginia Board of Medicine and the Virginia Department of Health, and authorizes a person to possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. Because an emergency exists, the act is in force from its passage. The protocols will be considered for adoption by the Board at the full Board meeting to be held on June 15, 2015.

To review these bills and others, visit *http://leg1.state.va.us* and search by bill number or keywords.

Most Commonly Cited Deficiencies During Routine Pharmacy Inspections

For the period of December 1, 2014 to February 28, 2015, a total of 151 routine pharmacy inspections were conducted. Of these, 35 (23%) pharmacies had no deficiencies, 56 (37%) had some deficiencies, and 60 (40%) had deficiencies that resulted in a monetary penalty and consent order. The most frequently cited Major Deficiencies for this period were:

1. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on hand at time of performing inventory or not noting an explanation for any difference between "physical count" and "theoretical count."
2. The incoming change of pharmacist-in-charge inventory was not taken as required or was substantially incomplete, such as not including all drugs in Schedules II-V.
3. Prescription drugs were stored outside of the approved prescription department.
4. No documentation of initial and annual (12 months) media-fill testing for persons performing low- and medium-risk level compounding of sterile products.
5. Pharmacist not documenting final verification of sterile compounding.

The most frequently cited Minor Deficiencies for this period were:

1. Not properly documenting partial filling of prescriptions.
2. Inventories taken on time, but not in compliance. Examples of noncompliance include the inventory not being signed and dated by the person taking the inventory; no indication whether the inventory was taken prior to the opening or after the close of business; Schedule II drugs are not listed separately from other scheduled drugs; and failure to include expired drugs in the inventory.
3. Required compounding, dispensing, or distribution records not complete and properly maintained.
4. Repackaging records and labeling are not kept as required or do not include all required elements.
5. No thermometer or a non-functioning thermometer in refrigerator or freezer.

The Pharmacy Inspection Report, Guidance Document 76-21.1, is available at *www.dhp.virginia.gov/enforcement/enf_guidelines.htm.* Guidance Document 110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide, is available at *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.*

Changes to Guidance Document 110-36

On March 24, 2015, the Board amended Guidance Document 110-36. The first amendment clarifies in item number 13 how often media-fill testing must be performed. Specifically, it states media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low- and medium-risk compounding, and semiannually for high-risk level compounding. **Note:** The terms "annually" and "semiannually" are defined within this guidance document to mean every 12 months and every six months, respectively. Annual media-fill testing must be performed no later than the last day of the twelfth month from the date of the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

The second amendment clarifies in item number 25 how often air and surface sampling must be performed. It now states that United States Pharmacopeia (USP) standards require air sampling to be performed at least every six months. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). USP requires surface sampling to be performed "periodically." The Board advises that surface sampling should be performed at least quarterly. It may be performed by pharmacy personnel or outsourced.

To read Guidance Document 110-36 in its entirety, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.*

continued on page 5

continued from page 4

Summary of Information Contained and Not Contained in a PMP Report

When querying the Virginia Prescription Monitoring Program (PMP), the report will list the covered substances dispensed to a specific patient during the requested time period. The term "covered substances" includes drugs in Schedules II-IV and any "drugs of concern" identified by the Board. Please note, however, that there are legal exemptions to the requirement for dispensers to report information to the PMP, and therefore, it is possible that the PMP report may not reflect every drug in Schedules II-IV that was dispensed or administered to the patient during the requested time frame. Pharmacists should take this into consideration when evaluating a patient's PMP report.

For example, a PMP report will not list the covered substances dispensed to the patient within a licensed narcotic maintenance treatment program, also known as a substance abuse treatment program or an opioid treatment program. Provisions within Title 42 Code of Federal Regulations Part 2 protect the identity of individuals receiving treatment in a substance abuse treatment program. The PMP report will also not list covered substances that were provided through pharmaceutical manufacturer programs; eg, manufacturer samples or drugs donated through an indigent patient program. Additionally, it will not list covered substances that may have been provided to the patient in a bona fide medical emergency. It will, however, list covered substances that were prescribed by an emergency department prescriber and dispensed elsewhere. The PMP report will not list covered substances that were administered to the patient in a prescriber's office or while an inpatient in a hospital, enrolled in a hospice program, or residing in a nursing home. The PMP report will, however, list the covered substances dispensed to a resident of an assisted living facility. Lastly, the PMP report will not list covered substances dispensed by a veterinarian to animals in the usual course of his or her practice, but it will list covered substances dispensed to an animal when dispensed by a pharmacy.

Electronically Transmitted Prescriptions

An "electronic prescription" means a written prescription that is generated on an electronic application and transmitted to a pharmacy as an electronic data file. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber that identifies him or her as the source of the message, and indicates his or her approval of the information contained in the message. If the prescription is generated electronically but then is printed out in the office and given to the patient, it is no longer an electronic prescription and it must follow the guidelines of a written prescription, to include bearing the prescriber's manual signature.

Effective June 1, 2010, Drug Enforcement Administration (DEA) issued interim final rules that authorized the electronic transmission of Schedule II-V prescriptions. Electronic prescriptions must meet all federal requirements including required security and authenticity features, as well as required record keeping for the prescriber and pharmacy. The application provider used by a prescriber or a pharmacy for electronic prescriptions of Schedule II-V drugs must be reviewed and certified by an approved certification body for compliance with DEA's standards. The application provider must provide a copy of this report to the pharmacy or prescriber using its services. A pharmacy or prescriber shall not dispense or issue an electronic prescription for Schedule II-V drugs until a report is received from the application provider indicating full compliance with DEA's standards.

Additional information regarding the federal rules for electronic transmission of prescriptions may be accessed at *www.deadiversion.usdoj.gov/ecomm/e_rx/index.html.*

Volunteer Pharmacists and Pharmacy Technicians Needed

Free clinics across the state are in need of volunteer pharmacists and pharmacy technicians. Pharmacists and pharmacy technicians can help clinics in a variety of ways to support patients in improving and maintaining their health, while ensuring free clinics continue to operate in the communities that need them. There are approximately 65 free clinics in Virginia; approximately 25 have pharmacies on site. To locate a free clinic in your area with a licensed pharmacy that participates with Rx Partnership, visit *www.rxpartnership.org/?page_id=84* or, for a complete list of clinics through the Virginia Association of Free and Charitable Clinics, visit *www.vafreeclinics.org/find-clinic*.

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